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**APR 11 2007
PATENT APPLICATION**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 3516.10US02

Sawhney

Confirmation No.: 9525

Application No.: 10/616,055

Examiner: Webman, E.

Filed: July 9, 2003

Group Art Unit: 1616

For: METHODS OF SUING IN SITU HYDRATION OF HYDROGELS ARTICLES FOR
SEALING OR AUGMNTATION OF TISSUE OR VESSELS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reasons stated on the attached sheets.

Remarks

Status of Claims

This reply is in response to the final Office Action dated August 21, 2006. Claims 1-69 are pending. Claims 9, 10, 32, 33, and 58 have been withdrawn, pending allowance of linking claims, in which case their re-entry and allowance is requested. Claims 1-8, 11-31, 34-57, and 59-69 stand rejected.

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Claims 1-8, 11-31, 34-37, and 59-69 were rejected under 35 U.S.C. §103(a) based on U.S. 5,843,743 (Hubbell) and U.S. 4,948,575 (Cole).

I. No prima facie case of obviousness was made out because the cited references do not provide all of the claimed features.

No prior art was disclosed in the Office Action with respect to the claimed volumetric expansion of at least about 20% (independent claim 53) or 50% (independent claims 1 or 41) after swelling with physiological fluid. Since not every claimed feature is set forth in the rejection or in the cited references, there is no prima facie case of rejection.

II. No prima facie case of obviousness was made out because there has been no showing that the that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

The Office Action, at page 2, argues that the claimed properties of hydration and shape to occlude a space upon hydration are inherent in the cited references because what is claimed is deemed to be obvious over the cited references. Hydration and shape are not the same as the amount of volumetric expansion, discussed above.

In the first place, this rejection is defective because the Office Action merely points to the references without providing a basis in fact or technical reasoning. As stated in MPEP 2112: "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."

In the second place, as argued in the November 17, 2006 Amendment at page 15, the cited references Hubbell and Cole do not disclose the claimed expansion of hydrogels or the claimed hydrogel having a substantially less than equilibrium level of hydration that is swellable with physiological fluid. For instance, Cole discloses making a foaming material on a wound area but does not disclose the claimed hydrogel having a substantially less than equilibrium level

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of hydration that is swellable with physiological fluid. Nor is there guidance in Hubbell or Cole for creating a desired degree of expansion, or the claimed amount of expansion. Nor is there guidance in Hubbell or Cole for choosing to make materials with the expansion that is claimed in combination with the shapes and structures that are claimed.

III. No prima facie case of obviousness was made out because there is no motivation to combine the cited references

There is no motivation to combine Cole and Hubbell to make the claimed invention because Cole teaches away from having a substantially less than equilibrium level of hydration for undergoing a volumetric expansion to occlude a lumen or void after swelling with a fluid from the body. Cole teaches that "If the dressing swells upon the absorption of fluids, this lack of dimensional stability may severely undercut the utility of these dressing for packing deep, heavily exuding wounds." Cole column 2 lines 45-48. Consequently, "When applied in or on a wound, the foaming action gently expands the dressing material conforming it to the shape of the cavity in, or the surface on, which it is applied.. The dressing material subsequently cures to a **dimensionally stable hydrogel** foam which exactly fits the wound." Cole, column 3, lines 19-25, emphasis added. The artisan reading Cole would understand that allowing swelling upon absorption of fluids was to be **avoided** because it could malfunction due to a "lack of dimensional stability" that would "severely undercut" the utility of the device. The artisan would understand that the foaming action, and not hydration, was to expand the dressing. Once the foaming action conformed the dressing to the shape of the material, it would be inoperable if it then swelled at least about 50% (independent claims 1 and 42) or 20% (independent claim 53).

This Argument, which was advanced in the November 17, 2006 Amendment at page 16, was rejected in the most recent Office Action on the grounds that it failed because Cole states "may" which is a merely advisory teaching. The issue, however, is if the artisan reading Cole would be motivated to make what is claimed in combination with Hubbell. The artisan reading

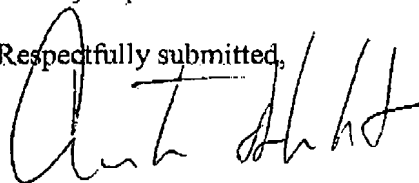
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these references would conclude that it could be acceptable to let the foam expand the dressing to the shape of the wound but would surely heed the warning that the hydrogel of the dressing should not be allowed swell with fluids; after all, once the foam had been used to achieve the best shape, allowing it to swell out of position would cause the device to become inoperative as a wound dressing.

Request for Allowance

Allowance of all of the claims is respectfully requested.

Respectfully submitted,



Curtis B. Herbert, Ph.D., Esq.
Registration No. 45,443

Customer No. 62274
Dardi & Associates
US Bank Plaza, Suite 2000
220 South 6th Street
Minneapolis, Minnesota 55402
Telephone: (612) 605-1038

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I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 571-273-8300 on the date shown below.

April 11, 2007

Date


Curtis B. Herbert, Ph.D., Esq.